

EXHIBIT A

Current
Version 3

4/3/2006

Lilly

Answers That Matter.

LillyUSA and the Global Marketing & Sales Organization (GMSO) Marketing - Compliance Policies and Procedures Promotional Materials

MAR-P-CPP 01-002

Objective: To set forth a policy and procedures regarding the development, approval, and maintenance of promotional materials to foster compliance with all applicable laws, regulations, government or court orders or decrees, and company policies.

Scope: All marketing and marketing support personnel based in the United States, including Puerto Rico, as well as all marketing activities that take place in the United States, including Puerto Rico, or with US Healthcare Professionals.

Policy Statement: It is the policy of LillyUSA and GMSO to comply with all applicable laws, regulations, government or court orders or decrees, and company policies regarding the development, approval, and maintenance of promotional materials.

Definitions

"Coming Soon" Advertising:

Information announcing the name of a product that will be available soon. A "coming soon" advertisement does not make written, verbal, or graphic representations, suggestions, or claims concerning the safety, efficacy, or intended use or targeted disease state of the product.

Consumer:

Any individual who does not meet the definition of a Healthcare Professional.

**Direct-To-Consumer (DTC)
Advertising:**

Information directed to consumers to increase their awareness about diseases, educate them about treatment options, and motivate them to contact their Healthcare Professionals and engage in a dialogue about health concerns. Goals of direct-to-consumer advertising include increasing the likelihood that consumers will receive appropriate care for conditions that are frequently under-diagnosed and under-treated, and encouraging compliance with prescription drug treatment regimens. Media environments for direct-to-consumer advertising include print, radio, and television.

**Direct-To-Consumer (DTC)
Materials:**

Items that have been approved for distribution directly to a consumer. Examples include patient education brochures, pamphlets, and pillboxes. Not all patient education materials are approved for distribution directly to a consumer. Some materials are intended for Lilly to distribute to Healthcare Professionals and then for Healthcare Professionals to give the materials to patients.

**Educational or Practice
Related Item for Healthcare**

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Professionals (EPRI):

Any item given to a Healthcare Professional that:

- primarily benefits the Healthcare Professional's patients; or
- is reasonably related to the practice of medicine; or
- serves a genuine educational or medical function.

Healthcare Professional (HCP):

Any physician, physician's assistant, nurse, nurse practitioner, nurse educator, diabetes educator, clinical psychologist, clinical investigator, research scientist, pharmacist, Pharmacy and Therapeutics Committee (P&T) member, social worker, case worker, dietitian, office staff, or any individual involved in prescribing, P&T, access, formulary, purchasing and/or reimbursement decisions.

Homemade Material:

Any material that has not been approved through the Lilly Promotional Materials Approval Process.

"Institutional" Advertising:

Information stating that the company is conducting research in a certain therapeutic area to develop new and important drugs. An "institutional" advertisement does not describe specific indications, mention any drug name (proprietary or established), or make any claims or suggestions of safety or efficacy.

Promotional Material:

Any item with a product name, logo, disease state, or a claim (message) used to promote a Lilly product or disease state treated by a Lilly product.

Reminder Advertisement:

An item that mentions the brand and generic name and/or logo of a drug but does not include indications, dosage recommendations, or characterize the drug in any way.

Sponsorship Advertisement:

A specific type of reminder advertisement including supporting an event, activity, or organization.

General Information

- Examples of promotional items include, but are not limited to:
 - DTC advertisements
 - DTC materials
 - Promotional brochures
 - Package inserts
 - Sales aids
 - Journal advertisements
 - Telecommunication advertisements
 - Videos, CD-ROMs, DVDs
 - Reprints of published articles
 - Scientific or other abstracts
 - EPRI's
 - All EPRI's must comply with MAR-P-CPP 01-008 Educational or Practice Related Items for Healthcare Professionals.

- Materials for presentation to HCPs during FDA-regulated programs (See MAR-P-CPP 01-016 FDA-Regulated Speaker Programs.)
- Materials for presentation to P&T committees, formulary committees, managed care organizations, hospitals, home healthcare companies, and institutions
- For promotional materials to meet FDA requirements for product claims, the materials must:
 - Include full prescribing information (package insert) or a brief summary of this information.
 - The brief summary must reference side effects, warnings, precautions, contraindications, and effectiveness about the advertised dosage form or indication.
 - Contain fair balance.
 - **NOT** be false or misleading.
 - Be within or consistent with approved product labeling.
 - Have proper support for claims.
 - Use data appropriately.
 - Provide adequate directions for use.
 - Be submitted to the FDA at or before time of first use.
- All DTC advertisements must comply with PhRMA Guiding Principles on Direct to Consumer Advertisements About Prescription Medicines and any additional Lilly guidelines on DTC advertisements. (Contact US Marketing Services to obtain any Lilly-specific DTC advertising guidelines.)

Lilly Promotional Materials Approval Process

- All promotional materials must comply with the company Standards for Preparation, Review, Approval, and Use of Promotional Material.
- The form and content of all promotional materials, including "Coming Soon" advertisements and institutional advertisements, for use in the US must be approved through the Lilly Promotional Materials Approval Process and submitted to the FDA at or before the time of first use, where appropriate.
 - Certain materials may also have to be submitted to the FDA for clearance in advance of use as determined by the FDA requirements and through the Lilly Promotional Materials Approval Process.
- Review of proposed promotional materials through the Lilly Promotional Materials Approval Process facilitates and documents the review, editing, and sign off by representatives from Marketing, Medical, Legal and Regulatory. The process also provides a mechanism for timely submission to the FDA if required.

Marketing's Responsibilities in the Promotional Materials Approval Process

- A Marketing team must initiate the Lilly Promotional Materials Approval Process for any proposed promotional item by preparing copies for all approvers.
 - All reprints, reports, etc. that serve as background or are referenced in the copy must accompany the promotional material through the approval process, or be readily available for use by the approvers.
 - Any item requiring any type of validation (e.g., dosing calculator, cooler bag) must be validated prior to commencing the Lilly Promotional Materials Approval Process.

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Legal's Responsibilities in the Promotional Materials Approval Process

- Legal will consult on legal issues related to promotional materials based on a pre-defined checklist of specific issues, and as needed per the team.
 - A checklist will be included as part of the Lilly Promotional Materials Approval Process, and it must be signed (with Initials and date) by the respective Marketing Manager indicating if a Legal consult is triggered.
 - The Marketing Editor is responsible for highlighting what information needs to be reviewed by Legal and for routing it to Legal for review.
 - If consulted, Legal will sign off on the checklist.
- Legal must be consulted and review proposed promotional material if it contains information on any of the following:
 - Price/pricing (e.g., rebates, contracting)
 - Reimbursement (e.g., Medicare, Medicaid, third-party payor)
 - Indigent programs
 - Changes to approved:
 - Fair balance language
 - Information about adverse events
 - Brief summary
 - Comparative or superiority claims (i.e., comparing a Lilly product to any other product, including comparative or superiority health economic claims)
 - Information about actual patients or other patient privacy concerns
 - Marketing to contact Virtual Privacy Office first; Legal consult only if required by VPO
 - Materials for medical reference binders
 - Significant new promotional strategy or message
 - Promotional use of new data
 - Any direct-to-consumer campaign
 - New copyright or trademark issues
 - Materials related to alliance partnership or co-promotion activities
 - Any other issues identified by brand attorney unique to a particular product

Medical's Responsibilities in the Lilly Promotional Materials Approval Process

- The Medical reviewer must review promotional materials for medical accuracy and compliance, including checking "Data on File" and all other relevant references.

Regulatory's Responsibilities in the Lilly Promotional Materials Approval Process

- The Regulatory reviewer must review promotional materials for any issues that might conflict with current full prescribing information or interfere or conflict with ongoing label discussions with the FDA.

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- The Regulatory reviewer must also review for violations of promotional/advertising regulations and consider information gained through surveillance of the external environment (e.g., enforcement letters sent by DDMAC).

Required Signatures

- For a proposed promotional material to be approved, representatives of Marketing, Medical, and Regulatory are required to sign off on the item based on the respective roles outlined above.
- For all promotional materials related to EVISTA, Regulatory or Legal must review the material for compliance with any applicable government/court orders and FDA requirements. This review must be documented (in writing or electronically).

Revisions to Previously Approved Promotional Material

- Any revisions to a previously approved promotional item must be approved through the Lilly Promotional Materials Approval Process.

Reminder Advertisements and Exact Re-Orders

- All reminder advertisements and exact re-orders of previously approved promotional materials relating to EVISTA must be approved through the Lilly Promotional Materials Approval Process.
- For all products other than EVISTA, only the Marketing Manager and Editor are required to sign off on reminder advertisements (other than Direct-to-Consumer reminder advertisements) and exact re-orders of previously approved promotional materials. The Editor may determine that review by Medical and Regulatory is not required by entering "N/A" on the approval form.
 - **NOTE:** Direct-to-Consumer reminder advertisements for all products are required to receive full review by all functions.

Maintenance of Promotional Materials

- A Marketing team must either destroy or update materials that do not reflect needed changes due to possible immediate and serious adverse health consequences or regulatory concerns.
 - For any materials requiring destruction, the Marketing team must provide an implementation guide to sales and field-based B2B personnel regarding the destruction.
- All promotional material must undergo periodic review and approval, at least annually, to assure that the material is still consistent with current knowledge, full prescribing information, and regulatory requirements.
- The Inventory Management Associate must:
 - Provide the Marketing teams detailed inventory reports at least annually.
 - Facilitate an annual process to ensure the Marketing teams review their stock of promotional materials to determine if items need to be updated or destroyed. (The Marketing teams are the owners of the inventory.)
- The Marketing teams must:
 - Complete a review, at least annually, of all items in their inventory, including items posted on Knowledge Management (KM), and meet agreed upon timelines for completion of review and updates.

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- Consult with Regulatory to ensure all materials are in compliance with any applicable government/court orders and FDA requirements.
- Ensure that all materials have an updated copy of the full prescribing information, as needed.
- Initiate a destruction notice for excess quantities of an item (i.e., amount held in excess of twelve months of demand).
 - For any materials requiring destruction in the field, the Marketing team must provide an implementation guide to sales and field-based B2B personnel regarding the destruction.
- Document (in writing or electronically) the review and disposition of all promotional items in stock.

Reminder Advertisements

- Except for sponsorship advertisements, television broadcast reminder advertisements are not allowed.
- Reminder advertisements are NOT allowed for any product with a boxed warning.
- A reminder advertisement may contain only the following information:
 - Drug Name
 - Quantitative Ingredients
 - Drug Price
 - Manufacturer's Name and Address
 - Graphics that do NOT imply a drug characteristic
- Reminder advertisements are exempt from the requirement to include full prescribing information or a brief summary.

Homemade Materials

- Use of homemade materials (i.e., materials NOT approved through the Lilly Promotional Materials Approval Process) with customers is forbidden.
- Examples of homemade materials include, but are not limited to:
 - Magazine, journal, or newspaper articles
 - Internet materials
 - PowerPoint presentations
 - Symposium materials
 - Product summaries
 - Price comparison sheets
 - Any item containing a product name
 - Sales training materials or other internal documents not intended for use with customers, including those marked "Not for Use in Detailing" or "For Internal Use Only"
 - Any change or alteration to an approved promotional item (e.g., highlighting, underlining, adding notes)

- Approved promotional materials may be laminated with a clear cover to protect them, but only if the original content, format, and organization is maintained.

Policy Owners: Vice President, Global Brands
Vice President, US Sales and Marketing, Business to Business
Vice President, US Sales and Marketing, Diabetes
Vice President, US Sales and Marketing, Neuroscience
Vice President, US Sales and Marketing, Specialty

Policy Custodians: Directors of Compliance & Ethics

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NOTE: If you are using a printed copy of this document, check that the version number is consistent with the current version number in Lotus Notes Marketing Compliance Policies and Procedures.

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